



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2018-0517; FRL-9980-76]

FIFRA Scientific Advisory Panel; Notice of Public Meeting and Request for Nomination of Ad Hoc Expert Members

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: There will be a 4-day, in-person meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) to consider and review the Evaluation of a Proposed Approach to Refine the Inhalation Risk Assessment for Point of Contact Toxicity: A Case Study Using a New Approach Methodology (NAM). Preceding the in-person meeting, there will be a half-day virtual preparatory meeting, conducted via webinar using Adobe Connect, to consider and review the clarity and scope of the meeting's draft charge questions. In addition, EPA is requesting nominations of prospective candidates for service as ad hoc members of FIFRA SAP for this meeting. Any interested person or organization may nominate qualified individuals to be considered as prospective candidates for this meeting by following the instructions provided in this document.

DATES: *Meeting:* The 4-day, in-person meeting will be held December 4 to December 7, 2018, from approximately 9 a.m. to 5 p.m.

Nominations: Nominations of candidates to serve as ad hoc members of the FIFRA SAP for this review should be provided on or before [*insert date* 30 days *from date of publication in the Federal Register*].

Special accommodations: Requests for special accommodations should be submitted on or before November 16, 2018, to allow EPA time to process your request.

Comments: Written comments should be submitted on or before October 19, 2018, and EPA encourages individuals and groups that wish to make oral comments to submit the request to make oral comments by November 9, 2018.

ADDRESSES: *Meeting:* The in-person meeting will be held at the Environmental Protection Agency, Conference Center, Lobby Level, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA 22202. The virtual meeting will be webcast. Please refer to the following website for information on how to access the webcast: <http://www.epa.gov/sap>.

Nominations: Submit nominations of candidates to serve as ad hoc members of the FIFRA SAP Meeting to the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

Special accommodations: For information on access or services for individuals with disabilities, and to request accommodation for a disability, please contact the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT**.

Comments. Submit requests to present oral comments to the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

Submit your written comments, identified by docket identification (ID) number EPA-HQ-OPP-2018-0517, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not electronically submit any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional information on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

For additional instructions related to this meeting, see Unit I.C. of the

SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT: Dr. Marquee D. King, DFO, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 202-564-3626; email address: king.marquee@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may be of interest to persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA) and FIFRA. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit CBI information to EPA through regulations.gov or email. If your comments contain any information that you consider to be CBI or otherwise protected, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting your comments.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

C. How May I Participate in both Meetings?

You may participate in both meetings by following the instructions in this unit. To ensure proper receipt of comments, nominations or other requests by EPA, it is imperative that you identify docket ID number EPA-HQ-OPP-2018-0517 in the subject line on the first page of your request.

1. *Written comments.* Written comments for both the in-person and virtual meetings should be submitted, using the instructions in **ADDRESSES** and Unit I.B., on or before October 19, 2018, to provide FIFRA SAP the time necessary to

consider and review the written comments. FIFRA SAP may not be able to fully consider written comments submitted after October 19, 2018.

2. *Oral comments.* To be included on the meeting agenda, the Agency encourages each individual or group wishing to make brief oral comments to FIFRA SAP during the in-person or virtual meetings to submit their request to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before November 9, 2018. To the extent that time permits, the Chair of the FIFRA SAP may permit the presentation of oral comments at the meeting by interested persons who have not previously requested time. Oral comments during the virtual meeting are limited to approximately 5 minutes due to the time constraints of this webcast. Oral comments during the 4-day, in-person meeting are limited to approximately 5 minutes unless arrangements have been made prior to November 9, 2018. The request should identify the name of the individual making the presentation, the organization (if any) the individual will represent, and any requirements for audiovisual equipment. In addition, each speaker should bring 15 copies of his or her oral remarks and presentation slides (if required) for distribution to the FIFRA SAP at the meeting by the DFO.

3. *Seating at the meeting.* Seating at the in-person meeting will be open and on a first-come basis.

4. *Request for nominations to serve as ad hoc expert members of FIFRA SAP for this meeting.* As part of a broader process for developing a pool of candidates for each meeting, FIFRA SAP staff routinely solicits the stakeholder community for nominations of prospective candidates for service as ad hoc

members of FIFRA SAP. Any interested person or organization may nominate qualified individuals to be considered as prospective candidates for a specific meeting. Individuals nominated for this meeting should have expertise in one or more of the following areas: (i) development and implementation of new approach methodologies (NAMs); (ii) inhalation alternative testing; (iii) inhalation toxicology; (iv) inhalation exposure assessment; (v) inhalation/computational fluid dynamic (CFD) modeling; and (vi) risk assessment. Nominees should be scientists who have sufficient professional qualifications, including training and experience, to provide expert comments on the scientific issues for this meeting. Nominees should be identified by name, occupation, position, address, email address, and telephone number. Nominations should be provided to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before [*insert date 30 days from date of publication in the Federal Register*]. The Agency will consider all nominations of prospective candidates for this meeting that are received on or before that date. However, final selection of ad hoc members for this meeting is a discretionary function of the Agency.

The selection of scientists to serve on FIFRA SAP is based on the function of the Panel and the expertise needed to address the Agency's charge to the Panel. No interested scientists shall be ineligible to serve by reason of their membership on any other advisory committee to a Federal department or agency or their employment by a Federal department or agency, except EPA. Other factors considered during the selection process include availability of the potential Panel

member to fully participate in the Panel's review, absence of any conflicts of interest or appearance of loss of impartiality, independence with respect to the matters under review, and lack of bias. Although financial conflicts of interest, the appearance of loss of impartiality, lack of independence, and bias may result in disqualification, the absence of such concerns does not assure that a candidate will be selected to serve on FIFRA SAP. Numerous qualified candidates are identified for each Panel; therefore, selection decisions involve carefully weighing a number of factors, including the candidates' areas of expertise and professional qualifications and achieving an overall balance of different scientific perspectives on the Panel. In order to have the collective breadth of experience needed to address the Agency's peer review charge for this meeting, the Agency anticipates selecting approximately 13 ad hoc scientists.

FIFRA SAP members are subject to the provisions of 5 CFR Part 2634 -- Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture, as supplemented by EPA in 5 CFR part 6401. In anticipation of this requirement, prospective candidates for service on FIFRA SAP will be asked to submit confidential financial information which shall fully disclose, among other financial interests, the candidate's employment, stocks, and bonds, and where applicable, sources of research support. EPA will evaluate the candidate's financial disclosure form to assess whether there are financial conflicts of interest, appearance of a loss of impartiality, or any prior involvement with the development of the documents under consideration (including previous scientific peer review) before the candidate is considered further for service on FIFRA

SAP. Those who are selected from the pool of prospective candidates will be asked to attend the public meetings and to participate in the discussion of key issues and assumptions at these meetings. In addition, they will be asked to review and to help finalize the meeting minutes and final report. The list of FIFRA SAP members participating at this meeting will be posted on the FIFRA SAP website at <http://www.epa.gov/scipoly/sap> or may be obtained from the OPP Docket at <http://www.regulations.gov>.

II. Background

A. Purpose of FIFRA SAP

The FIFRA SAP serves as one of the primary scientific peer review mechanisms of EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) and is structured to provide independent scientific advice, information and recommendations to the EPA Administrator on pesticides and pesticide-related issues as to the impact of regulatory actions on human health and the environment. FIFRA SAP is a Federal advisory committee established in 1975 under FIFRA that operates in accordance with requirements of the Federal Advisory Committee Act (5 U.S.C. Appendix). The FIFRA SAP is composed of a permanent panel consisting of seven members who are appointed by the EPA Administrator from nominees provided by the National Institutes of Health (NIH) and the National Science Foundation (NSF). FIFRA established a Science Review Board (SRB) consisting of at least 60 scientists who are available to FIFRA SAP on an ad hoc basis to assist in reviews conducted by FIFRA SAP. As a scientific peer review mechanism, FIFRA SAP provides comments, evaluations, and

recommendations to improve the effectiveness and quality of analyses made by Agency scientists. Members of FIFRA SAP are scientists who have sufficient professional qualifications, including training and experience, to provide expert advice and recommendation to the Agency.

B. Public Meeting

EPA conducts human health risk assessments to evaluate the potential health effects of pesticides and toxic chemicals in residential and occupational settings based on the use pattern or conditions of use. For evaluating effects via the inhalation route, registrants and manufacturers conduct subchronic inhalation toxicity studies according to test guideline requirements (OPPTS 870.3465, 40 CFR Part 798, OECD TG 412 and 413). In these studies, several groups of experimental animals are exposed daily for a defined period to graduated concentrations of test substance as a gas or aerosol/particulate. These studies are used to determine a no observed adverse effect concentration (NOAEC) for effects following repeated inhalation exposure that may be used for human health risk assessment.

The anatomy and physiology of human and animal respiratory tracts differ in several ways that can impact changes in airflow and deposition of inhaled substances and, therefore, influence the animal to human dose response extrapolation. Furthermore, traditional *in vivo* toxicity tests used to extrapolate from test species to humans are expensive, time-consuming, and can cause stress to laboratory animals. As a result, efforts to develop alternative methods and strategies for evaluating toxic effects from inhaled chemicals using *in vitro* test

systems with human tissues combined with human dosimetry modeling provide inherent advantages over using *in vivo* animal studies. These alternatives are also consistent with the National Research Council's (NRC) long-range vision to advance toxicity testing in the 21st century, as well as the strategic roadmap released by Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) to accomplish NRC's vision in the United States.

New approach methodologies (NAMs) has been adopted as a broadly descriptive reference to any non-animal technology, methodology, approach, or combination thereof that can be used to provide information on chemical hazard and risk assessment. An example of a NAM for refining inhalation risk assessment has been submitted to the Agency for the pesticide chlorothalonil. Chlorothalonil is a contact irritant that has been found to be toxic via the inhalation route. Due to the irritant nature of chlorothalonil and animal welfare concerns, the registrant (Syngenta Crop Protection) indicated that a 90-day inhalation toxicity study was not feasible to fulfill the regulatory requirement of a subchronic inhalation study. Subsequently, Syngenta proposed an alternative approach using an *in vitro* assay (MucilAir™ using human nasal tissue) to characterize the hazard of chlorothalonil and derive a point of departure (POD) for use in human health risk assessment. In order to calculate human equivalent concentrations for the purposes of human health risk assessment, an *in vitro* POD has been proposed in conjunction with surface concentrations of deposited chlorothalonil particles from a computational fluid dynamic (CFD) model for the upper airway of a human. As a proof of concept, Syngenta also used the

calculated human equivalent concentrations for pesticide operators/applicators to provide potential risk estimates supported by this proposed approach.

The Agency is soliciting advice from the FIFRA Scientific Advisory Panel (SAP) on the derivation of the POD from the in vitro assay and the integration of the in vitro POD for calculation of human equivalent concentrations for the inhalation risk assessment. Chlorothalonil will be presented as a case study to solicit advice on the proposed overall approach expected to be applied to other pesticides or industrial chemicals in the future.

The 4-day, in-person FIFRA SAP meeting may also be webcast. You may refer to the FIFRA SAP website at <http://www.epa.gov/sap> for information on how to access the webcast. Please note that the webcast for the in-person meeting is a supplementary public process provided only for convenience. If difficulties arise resulting in webcasting outages, the in-person meeting will continue as planned.

C. Virtual Preparatory Meeting

Preceding the in-person meeting, there will be a half-day virtual preparatory meeting, conducted via webinar using Adobe Connect, to consider and review the clarity and scope of the meeting's draft charge questions. The virtual preparatory meeting will be webcast only, and registration is required to attend this virtual meeting. The date and registration instructions will be announced in a future **Federal Register** Notice and on the FIFRA SAP website (<http://www.epa.gov/sap>) by mid-September.

D. FIFRA SAP Documents and Meeting Minutes

EPA's background paper, charge/questions to FIFRA SAP, and related supporting materials will be available by early September 2018. In addition, a list of candidates under consideration as prospective ad hoc panelists for this meeting will be available for a 15-day public comment period by early to mid-September 2018. You may obtain electronic copies of most meeting documents, including FIFRA SAP composition (i.e., members and ad hoc members for this meeting) and the meeting agenda, at <http://www.regulations.gov> and the FIFRA SAP website at <http://www.epa.gov/scipoly/sap>.

FIFRA SAP will prepare the meeting minutes and final report approximately 90 calendar days after the in-person meeting. The meeting minutes and final report will be posted on the FIFRA SAP website:

<https://www.epa.gov/sap> and may be accessed in the docket at <https://www.regulations.gov>.

Authority: 7 U.S.C. 136 *et. seq.*; 21 U.S.C. 301 *et seq.*

Dated: July 12, 2018.

Stanley Barone, Jr.,

Acting Director, Office of Science Coordination and Policy.

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